



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,228	09/29/2003	Samir M. Hanash	31755-A-PCT-USA-I	1891
38485	7590	03/02/2006	EXAMINER	
ARENT FOX PLLC 1675 BROADWAY NEW YORK, NY 10019			YU, MISOOK	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,228

Applicant(s)

HANASH ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims 5-21, drawn to an invention nonelected with traverse in the reply filed on 06/06/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 5-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) for reason of record.

Claims 1-21 are pending and claims 1-4 are examined on merits.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Maintained

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirsch et al., IDS filed on 07/11/2005, J Cancer Res Clin Oncol. 1988;114(2):204-7.

Claims 1-4 are drawn to method of identifying proteins that induces autoantibodies in cancer patients, comprising the steps of isolating proteins from cancer cells, more specifically cells derived from the subject's tumor (claim 2), or from a continuous cell line representative of the subject's tumor (claim 3), followed by subjecting isolated proteins to two-dimensional PAGE, followed by Western blot analysis with sera from cancer patients as compared to sera from normal control

patients, wherein the proteins bound by antibodies present in the cancer patients serum but not the normal control serum are identified as proteins to which a subject with cancer produces autoantibodies. Since the specification does not defined the limitation "derived from the subject's tumor" in claim 2 and "derived from a continuous cell line representative of the subject's tumor" in claim 3, the limitations are broadly interpreted as the cells that are being used to isolate the proteins being subjected to two-dimensional analysis are from the same type of cancer cells as the patient who provides the serum containing autoantibodies.

Applicant argues that a one-dimensional gel electrophoresis before transferring proteins to nitrocellulose by the Western blot technique is used, followed by testing sera from patients with Hodgkin's disease for antibody reactivity in Hirsch et al. Applicant argues that Hirsch et al., do not discloses the use of two-dimensional electrophoresis to find proteins that had not been found by one-dimensional electrophoresis. Applicant argues that Hirsch et al., do not disclose the comparison of proteins to which antibodies in the subject serum binds vs. in the control sample.

These arguments have been fully considered but found unpersuasive because the instant claims are construed with the open transitional phrases of "comprising", which does not exclude any unrecited steps or element. In other words, the instantly claimed method does not exclude one-dimensional gel electrophoresis.

As stated in the previous Office action, Hirsch et al., at method of identifying proteins that induces autoantibodies in Hodgkin's disease which is a form of cancer, i.e. lymphoma, comprising the steps of isolating proteins from L428 cancer cells derived

from Hodgkin's disease cancer patients, followed by subjecting isolated proteins to two-dimensional PAGE, followed by Western blot analysis with sera from cancer patients as compared to sera from normal control patients (see abstract, where it shows that p-65 did not bind to 54 samples out of 55), wherein the proteins bound by antibodies present in the cancer patients serum but not the normal control serum are identified as proteins to which a subject with cancer produces autoantibodies. Note page 204 under the heading Materials and methods for the gel-electrophoresis, and Western blot, and the picture of the identified proteins in the two-dimensional gel at Fig. 1A, 2, 3.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

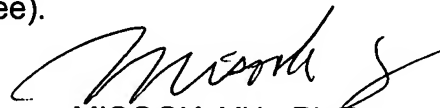
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642